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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/586,191 | 07/14/2006 | Hiromitsu Fuse | 023312-0127 | 2427 |
| 22428 7590 03/13/2008 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007 | | | | |
| EXAMINER | | | | |
| WOLLENBERGER, LOUIS V | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1635 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 03/13/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/586,191

Applicant(s)

FUSE ET AL.

Examiner

Louis Wollenberger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16, 18, 20-31, 34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 11-14, 16, 18 and 20-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10, 28-31, 34 and 35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: Exhibit A: Printout from NCBI MeSH database

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-10, 28, 29, 30, 31, 34, and 35, drawn to a medicament comprising an inhibitor of GM3 synthase gene expression for prevention/treatment of atherosclerosis, including embodiments thereof wherein the inhibitor is an antisense polynucleotide, siRNA, or shRNA, and to methods of use thereof in the reply filed on 12/26/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 11-14, 16, 18, and 20-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/26/07.

Claims 1-10, 28, 29, 30, 31, 34, and 35 are under consideration and subject to further restriction as follows.

Upon preliminary examination of the elected claims, it has become clear that claims 1-10, 28-31, 34, and 35 lack unity of invention *a posteriori*, for the reasons given below. Therefore, Restriction is required under 35 U.S.C. 121 and 372.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect one of the following inventions to which the claims must be restricted:

Group Ia, claim(s) 1-10, 34, and 35, drawn to a medicament comprising an inhibitor of GM3 synthase gene expression for prevention/treatment of atherosclerosis, including embodiments thereof wherein the inhibitor is an antisense polynucleotide, siRNA, or shRNA.

Group Ib, claim(s) 28-31, drawn to a method for preventing/treating atherosclerosis comprising inhibiting the expression of GM3 synthase.

The inventions listed as Groups Ia and Ib do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of Groups Ia and Ib is an inhibitor of GM3 synthase gene expression. However, this cannot be the special technical feature because the feature is taught and suggested by the prior art.

Whether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," should be considered with respect to novelty and inventive step (MPEP 1850.II).

In the instant case GM3 Synthase inhibitors are taught by the prior art. For example, Cambron et al. (1993) *Biochem. Biophys. Res. Comm.* 193:585-590 taught that UDP-dialdehyde effectively inhibits SAT-1, also known as CMP-N-acetylneuraminic acid:lactosylceramide sialyltransferase, also known as GM3 Synthase (see accompanying Exhibit A: Printout from McSH Database downloaded from NCBI on 3/4/08).

Additionally, in view of Tuschl et al. (US 2004/0259247 A1) (paragraphs 29 and 30) and Vickers et al. (2003) *J. Biol. Chem.* 278:7108-7118 (pg. 7117, right column), who taught that siRNAs and antisense oligonucleotides alike may be used to investigate gene function in vitro, it

would have been obvious at the time of invention to make and use antisense oligonucleotides and siRNAs against the gene encoding GM3 synthase to investigate GM3 synthase function in vitro and in vivo. The gene encoding GM3 synthase was known (see Saito, US Patent 6,555,371, disclosing SEQ ID NO:7, which is identical to instant SEQ ID NO:2 and encodes a protein identical to instant SEQ ID NO:1), and it would have been well within the level of skill of the ordinary artisan to design and use antisense oligonucleotides and siRNAs against any known gene, including GM3 synthase, at the time of invention.

Accordingly, Groups Ia and Ib lack unity of invention *a posteriori*.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/

Examiner, AU 1635

March 4, 2008